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TITLE: Relationships Between IGF-1, IGF-Binding Proteins and Diet in African American and Caucasian Men

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The study aims to determine racial differences between IGF-1, IGFBP-2, IGFBP-3, PSA, testosterone, BMI, and diets high in calories, protein and fat. Specifically, the study objectives are to:

- define racial differences in serum levels of free and total IGF-1, IGFBP-2, IGFBP-3, and testosterone;
- define how diet and BMI impact serum levels of IGF-1, IGFBP-2, IGFBP-3, testosterone and PSA in African American and Caucasian men; and
- determine the associations between serum levels of free and total IGF-1, IGFBP-2, IGFBP-3, testosterone, PSA, BMI and specific nutrients.

The proposed study will help to explain the increased risk of prostate cancer for African American men and the role of specific nutrients in influencing IGF-1 and IGF-binding protein concentrations. This report covers primarily patient accrual activities during the first year of the project. These activities include finalizing the clinical protocol, hiring and training of study personnel, reviewing clinical questionnaires to determine study eligibility, and determination of stored frozen samples for use.

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## INTRODUCTION

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- define racial differences in serum levels of free and total IGF-1, IGFBP-2, IGFBP-3, and testosterone
- define how diet and BMI impact serum levels of IGF-1, IGFBP-2, IGFBP-3, testosterone and PSA in African American and Caucasian men.
- determine the associations between serum levels of free and total IGF-1, IGFBP-2, IGFBP-3, testosterone, PSA, BMI and specific nutrients.

The proposed study will help to explain the increased risk of prostate cancer for African American men and the role of specific nutrients in influencing IGF-1 and IGF-binding protein concentrations.

This report covers primarily patient accrual activities during the first year of the project. These activities include finalizing the clinical protocol, hiring and training of study personnel, reviewing clinical questionnaires to determine study eligibility, and determination of stored frozen samples for use.

## BODY

Progress in the study during the first year of funding will be described below with respect to each of the tasks in the original Statement of Work.

### Statement of Work

**Task 1: Months 1-3: Hiring and Training of Staff**

The grant was officially awarded December 1999, but did not start until April 2000 due to concerns expressed by the Human Subjects Protection, AMDEX Corporation. In March, a medical research assistant was employed to work on the project. Study protocol was finalized and a training session was held to discuss study goals, objectives, protocols, responsibilities and data collection procedures.

**Task 2: Months 3-4: Obtain and review clinical questionnaires of 1,517 men who participated in prostate screenings to identify men eligible for the study**

The clinical questionnaires were obtained from the men who participated in the prostate screenings. The questionnaires were categorized by race, age, and cancer status. Computer entries of all questionnaires were inputted in Microsoft Excel.

**Task 3: Months 4-5: Obtain PSA values for men who are eligible for the study.**

PSA results were obtained for all men and computer entry of results was inputted in Microsoft Excel.

**Task 4: Months 4-5: Work with Director of Serum Bank to retrieve serum for men eligible for the study.**

We are working closely with the Dr. Bruce Trock, Director of the Serum Bank, Lombardi Cancer Center, Georgetown University for the retrial of serum samples. Dr. Trock informed us that some of the stored samples were frozen in the wrong tubes, or stored as whole blood or were centrifuged, but not stored as serum. Therefore, we are conducting preliminary studies to determine the reliability and validity of IGF-1, IGFBP-2, and IGFBP-3 in whole blood when compared to serum. Samples

will be obtained from 10 volunteers participating in Dr. Trocks project. Dr. Kevin Cullen, who is an investigator with this project, will have his lab to conduct the comparative analysis. Results from the preliminary studies will help us to determine which frozen samples are appropriate for our study. The analysis will be completed within a few months. After completion of the analysis, we will proceed with analyzing IGF-1, IGFBP-2, IGFBP-3, testosterone and telephone interviewing.

**Task 5: Months 5-8: Analyze serum for IGF-1, IGFBP-2, IGFBP-3 and testosterone.**
Todate, serum has not been analyzed for IGF-1, IGFBP-2, IGFBP-3 and testosterone, until the comparative analysis of whole blood and serum has been completed.

**Task 6: Months 6: Stratify and randomize over 300 men for telephone interview.**
We have stratified over 300 questionnaires of men eligible for the telephone interview. However, we must have the serum for each subject interviewed, therefore we are waiting until the comparative analysis of whole blood and serum has been completed.

**Task 7: Months 6-8: Send letters to 300 men requesting telephone interview.**
Have not yet addressed.

**Task 8: Months 7-13: Call 300 men to schedule telephone interview.**
Have not yet addressed.

**Task 9: Months 8-20: Conduct telephone interview.**
Have not yet addressed.

**Task 10: Months 9-21: Mail monetary incentive to interviewees.**
Have not yet addressed.

**Task 11: Months 15-24: Data entry and analyze; complete final report.**
Have not yet addressed.

## KEY RESEARCH ACCOMPLISHMENTS

- Hiring and training of personnel working on project.
- Finalization of study protocol.
- Obtained and reviewed clinical questionnaires of 1,517 men who participated in prostate screenings to identify men eligible for the study.
- Obtained PSA values for men who are eligible for the study.
- Data entry of clinical information from questionnaires and PSA values.

## REPORTABLE OUTCOMES

None at this time.

## CONCLUSIONS

Study efforts in this first year have focused on process issues. Unanticipated obstacles in sorting out which frozen samples are appropriate for study analysis in underway. To address this issue we are conducting a preliminary analysis to compare the validity and reliability of IGF-1, IGFBP-2, and IGFBP-3 in whole blood versus serum. Based on these results we can determine which samples are appropriate to use for our study.

Study personnel was hired and trained. The clinical protocol was finalized and over 1500 clinical questionnaires have been reviewed to determine study eligibility. Data entry of clinical information and PSA's are completed for all eligible subjects.

# APPENDICES

## LIST OF ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| IGF | insulin growth factor type 1 |
| IGFBP-2 | insulin growth factor binding protein 2 |
| IGFBP-3 | insulin growth factor binding protein 3 |
| PSA | prostate-specific androgen |

**Meeting abstracts during reporting period:** None in connection with this project

**Publications during reporting period:** None in connection with this project

**Manuscripts in preparation:** None in connection with this project

**Personnel receiving pay from this negotiated effort**:

Tanya Agurs-Collins, Ph.D.
Cheryl Wise